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ORIGINAL RESEARCH ARTICLE

Information on early medical abortion for women using an audiovisual animation versus face-to-face consultation: A consortium randomized and quasi-randomized trial

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Abstract

Introduction: There is some evidence that audiovisual formats can be an effective way of providing information about early medical abortion (EMA). A short animation (3 minutes) was developed about EMA in three languages that summarized the EMA process for use in the UK, France and Sweden.

Material and methods: We conducted a multicenter randomized controlled trial to compare information on EMA delivered by an animated film versus a face-to-face consultation. Women requesting EMA (≤ 9 weeks' gestation) from abortion clinics in Edinburgh (UK), Paris (France) and Stockholm (Sweden) were recruited. The primary outcome was women's recall of prespecified key information on EMA. Secondary outcomes were acceptability of mode of information delivery, clarity and helpfulness of information rated on a Likert scale. The study was prospectively registered with clinicaltrials.gov, ID number: NCT03417362.

Results: 172 women completed the study (Edinburgh = 50, Paris = 78, Stockholm = 48). There was no statistically significant difference in recall scores between the animation and standard arms in Edinburgh and Stockholm sites. However, the difference between arms at the Paris site was statistically significant ($P = .007$) in favor of the animation. All participants in the animation arm rated it as an acceptable way to receive information on EMA.

Conclusions: A "short" audiovisual animation can adequately and acceptably deliver key information about EMA. This intervention could be used routinely to provide standardized and high-quality information to women seeking EMA.

KEYWORDS

contraception, early medical abortion, education, pregnancy, termination of pregnancy, women's health issues

Abbreviations: EMA, early medical abortion.

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1 | INTRODUCTION

In many parts of Europe, increasing proportions of all abortions are performed at <9 weeks' gestation using the early medical abortion (EMA) combined mifepristone-misoprostol regimen.¹ Typically, the clinical consultation with women seeking EMA involves medical history-taking and provision of extensive information on this method of abortion. Future contraceptive methods are also discussed. This consultation can be lengthy and much of this time consists of provision of verbal information. Although much information can also be imparted by written patient information leaflets, there are concerns that a significant proportion of women seeking abortion may not read these. In one study, it was reported that 14% did not read the detailed patient information leaflet on abortion and what it involves.² Furthermore, rates of low literacy in some settings are important. Data suggest that between 16% and 22% of adults aged 16-65 across Europe have problems reading and so may not understand the contents of a written information leaflet.³

In contrast, there is evidence that provision of audiovisual information about abortion via a video is rated by women as highly informative and favorable when compared with written information leaflets.² Additionally, abortion care providers have reported that women who have received information this way are better prepared and informed about what abortion involves, allowing consultations to progress more easily and greater time for discussion of future contraceptive methods.² There is further evidence (from women requesting an abortion) that information on contraceptive methods can also be effectively delivered in an audiovisual format and that they feel more confident about the chosen contraceptive method than those who only discuss the method with a clinician (without seeing a video).⁴

We developed an audiovisual animation of approximately 3 minutes' duration to provide core information about EMA. The content of this animation was based on guidance from Royal College of Obstetrics and Gynaecology (RCOG)⁵ on what women need to know prior to attending an abortion clinic appointment, national guidelines in Sweden and France and the expert opinion of the multinational investigator team for this study. The animation summarized the process of EMA using simple language and animated characters representing women of diverse ages and ethnicities. The animation covered how to take the mifepristone and misoprostol medications, options of treatment at home, in clinic or in a hospital, post abortion follow up and future contraception.⁶ The animation was translated and recorded in French and Swedish and was adapted to reflect subtle differences in practice and law in France and Sweden. Our aim was to determine how the animation compared in terms of information provided about EMA in a typical face-to-face consultation in Scotland, Sweden and France.

2 | MATERIAL AND METHODS

We conducted a randomized controlled trial with parallel assignment and an allocation ratio 3:7 (meaning that for a sample size of 50, there would be 15 participants in the standard arm: 35 participants

Key message

A short animation can deliver key information about early medical abortion as effectively as a face-to-face consultation with a clinician. An animated film on early medical abortion has the potential to replace or supplement some of the information provided to women during a consultation.

in the animation arm). Eligibility criteria for participation were women presenting for abortion up to 9 weeks' (63 days') gestation, aged 16 years or over (over 18 in Sweden), able to provide written consent and able to understand English/French/Swedish (depending on site) without the need for an interpreter.

Women were approached by research staff, who were not directly involved in patient care, once they had an ultrasound and/or gynecological examination confirming their gestation. They were given time to consider participation in the trial and to provide written informed consent. Women were randomized to a study arm by the research staff.

In the standard arm, participants had a face-to-face consultation with a clinic doctor or nurse/midwife as usual—these consultations involve a discussion about reasons for wanting an abortion (dependent on legal requirements for sites), clinical history, methods of abortion and practicalities of treatment. This was then followed by a researcher-administered questionnaire, prior to administration of mifepristone and departure from the clinic.

In the animation arm, participants watched the animation via a laptop computer in a private room in the clinic. This was immediately followed by a researcher-administered questionnaire. They then proceeded to have a face-face consultation with the clinic doctor or nurse/midwife as usual.

In both study arms, the questionnaire was adapted from previous published studies conducted at the Edinburgh site^{2,4} and asked participants to recall any important information about EMA and their expectations of EMA following the consultation or animation. There were also simple questions about demographics, baseline knowledge of abortion and how useful, clear and helpful they found the animation or consultation, respectively, indicated on a Likert Scale. Usefulness was rated on an 11-point scale from 0 to 10, with 0 being totally useless and 10 being extremely useful. Clarity and helpfulness were rated on 5-point scales, specified in the outcome measures below. For those in the animation arm, there were additional questions about acceptability of this method of information delivery and open-ended questions about what they liked and disliked about the animation.

There were three sites: abortion services in Edinburgh, UK (Chalmers Centre, with approximately 1900 attendances per annum); Stockholm, Sweden (Ultragyn, with approximately 1700 attendances per annum); and Paris, France (ipso Saint Martin, with approximately 400 attendances per annum). The study sites collaborated as a research consortium, each seeking regulatory approvals independently in their own country.

2.1 | Outcome measures

Our primary outcome measure was recall of key information about EMA assessed by points recalled by participant against a list of eight prespecified items selected by the research team that are covered by the animation and during routine consultation. These items are listed in Table 1. A score of 1 was given for each key item recalled, giving a maximum total score of 8. We considered each of these points to be important and so weighted them equally.

Our secondary outcome measures were helpfulness and clarity of the information rated on a 5-point Likert scale (eg very helpful, a bit helpful, neither helpful nor unhelpful, a bit unhelpful, very unhelpful); utility of the information received rated on an 11-point scale from 0 to 10; and acceptability of the animation on a 5-point Likert scale (animation arm only and rated very acceptable, a bit acceptable, neither acceptable nor unacceptable, a bit unacceptable, very unacceptable). Comments on positives and negatives of the animation were collated and categorized. These measures were all assessed using the researcher-administered questionnaire and these outcomes did not change after the trial commenced.

2.2 | Sample size

In Edinburgh and Stockholm, a sample size of 35 was allocated to the animation arm to allow estimation of percentage rates of acceptability and recall to within a standard error of around 8% within each center. The power for the randomized comparison to 15 controls was sufficient to give high power to detect a difference of around 40% between the two arms. The allocation of unequal numbers was to improve the precision of estimates within the animation arm without greatly reducing the power for the randomized comparisons.

2.3 | Randomization

At the Edinburgh and Stockholm sites, the random allocation sequence was generated by an independent statistician using SPSS random number generator and block sizes of 10. Sequentially numbered, opaque, sealed envelopes were prepared by the statistician, who was not directly involved in the research team. Envelopes were opened with each

participant once consent was obtained. Due to the nature of the intervention, the study was not blinded. At the Paris site, participants were quasi-randomized and allocated to study arm by year of birth—even-numbered years to animation and odd-numbered to standard care.

2.4 | Analysis

Chi-square, Mann-Whitney, Kruskal-Wallis and Spearman rank correlation tests were used depending on data types for between-group and within-group analyses. There were no interim analyses performed.

2.5 | Ethical approval

Ethical approval was sought at each site. In Edinburgh, approval was granted by the South East Scotland NHS Research Ethics Committee, reference: 18/SS/0014 (26 February 2018). In Stockholm, approval was given by the Stockholm, Regional Ethics Committee Dnr 2018/1042-31 (7 June 2018). In Paris, the study was internally reviewed by the governance team of the Department of Obstetrics and Gynecology and deemed not to require full ethical review. The study was prospectively registered with clinicaltrials.gov and assigned registration number NCT03417362.

3 | RESULTS

We recruited a total of 178 participants to the trial between 5 March 2018 and 12 March 2019 (Edinburgh = 50, Paris = 78, Stockholm = 54). In total, 200 eligible patients were approached to participate in the study (Edinburgh = 63, Stockholm = 54, Paris = 83). Six participants were randomized but subsequently withdrew consent to participate, all at the Stockholm site, three were in the animation arm, and three in the standard arm. Thus a total of 172 participants were included in the primary outcome analysis (Edinburgh = 50, Paris = 78, Stockholm = 48; Figure 1). Tables 2 and 3 show baseline demographic data for participants per site.

3.1 | Primary outcome—Recall

There was no statistically significant difference in recall scores between the animation and standard arms at the Edinburgh and Stockholm sites (Table 4). However, the difference between arms at the Paris site was statistically significant ($P = .007$) in favor of the animation. Differences between sites were statistically significant ($P < .001$).

3.2 | Secondary outcomes

There were no statistically significant differences between groups at any study site for ratings of clarity. There were no differences at

TABLE 1 Recall items of EMA that each scored 1 point

Only 1 visit to clinic required (ie no mandatory reflection period, return for medications, in-person follow up)
1st medication (mifepristone)
2nd medication (misoprostol) taken 1-2 days later
They should have an adult at home with them
A pregnancy test in 2 weeks to confirm success of procedure
Should start contraception straight away
Abortion is a common procedure
Pain and bleeding—may be like/worse than a “bad period”

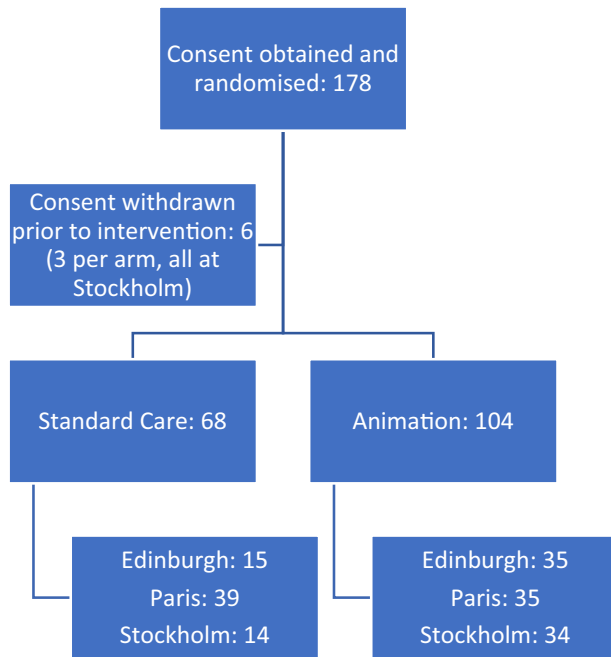


FIGURE 1 Flowchart of participants in study [Colour figure can be viewed at wileyonlinelibrary.com]

the Edinburgh or Stockholm sites for utility or helpfulness ratings; however, there were statistically significant differences in these ratings at the Paris site—utility rating favored the animation arm, but helpfulness favored the standard arm (Table 4). All participants in the animation group at all sites rated the animation as a very acceptable or quite acceptable way to receive information about abortion. The primary and secondary outcomes are summarized in Table 4.

3.3 | Open comments

Of the 104 participants in the animation arm, 100 offered positive comments about the animation and 21 offered negative comments (some participants offered both positive and negative comments). Comments on the clarity and simplicity of the animation were made at all study sites, as were positive comments about the diversity of characters shown in the animation. Of interest, the participants at the Paris site commented that the animation made them feel less guilty about having an abortion and reinforced the notion that it is a human right, more so than participants at other sites. Further details are given in Table 5.

4 | DISCUSSION

This is the first randomized controlled trial to compare and evaluate patient rating of an audiovisual animation with a face-to-face consultation for provision of information on EMA.

The study showed that this short audiovisual animation on EMA was comparable to a standard consultation in terms of recall of key information, clarity of information, utility of information and helpfulness. This may be surprising as the animation was only 3 minutes in duration and, although we did not record the timings of standard consultations for the study, they approximately range from 45 to 60 minutes at each service. However, our findings are consistent with those of studies using videos or animations in sexual and reproductive healthcare settings, to deliver information on abortion, contraception and sexual and reproductive healthcare more generally, where women found this mode of delivery as informative as standard consultations.^{2,4}

	Edinburgh (N = 50) n (%)	Paris (N = 74) n (%)	Stockholm (N = 48) n (%)	
Self-rated baseline knowledge of abortion as "knew a lot already"	18 (36%)	27 (36.5%)	23 (47.9%)	$P = .375$
Mean age in years	26.6	27.0	30.2	$P = .002$
Current smoker	21 (42%)	34 (45.9%)	7 (14.6%)	$P < .001$
Previous pregnancy	24 (48%)	34 (45.9%)	36 (75%)	$P = .004$
Previous abortion	17 (34%)	21 (28.4%)	29 (60.4%)	$P < .001$

TABLE 2 Baseline characteristics by site

	Standard (n = 68) n (%)	Animation (n = 104) n (%)	
Self-rated baseline knowledge of abortion as "knew a lot already"	26 (38.2%)	42 (40.4%)	$P = .902$
Mean age in years	27.8	28.0	$P = .708$
Current smoker	32 (47.1%)	30 (28.8%)	$P = .023$
Previous pregnancy	31 (45.6%)	63 (60.6%)	$P = .076$
Previous abortion	22 (32.4%)	45 (43.4%)	$P = .202$

TABLE 3 Baseline characteristics by study arm

TABLE 4 Study outcomes

Outcome	Site	Standard	Animation	Differences between arms
Recall (mean points recalled out of a maximum of 8)	Edinburgh	3.33	3.48	$P = .624$
	Paris	2.94	3.88	$P = .007$
	Stockholm	5.07	5.29	$P = .610$
Helpfulness (rated "very helpful") n (%)	Edinburgh	14 (93%)	34 (97%)	$P = .546$
	Paris	39 (100%)	26 (74%)	$P = .001$
	Stockholm	12 (86%)	27 (79%)	$P = .919$
Clarity (rated "very clear") n (%)	Edinburgh	14 (93%)	32 (91%)	$P = .820$
	Paris	30 (77%)	31 (89%)	$P = .313$
	Stockholm	9 (64%)	27 (79%)	$P = .463$
Utility (rated 10/10 for utility) n (%)	Edinburgh	9 (60%)	26 (76%)	$P = .768$
	Paris	26 (67%)	30 (86%)	$P = .048$
	Stockholm	9 (64%)	23 (68%)	$P = .441$
Differences between sites				
Acceptability of animation (rated "very acceptable")	Edinburgh		30 (86%)	$P = .216$
	Paris		31 (89%)	
	Stockholm		25 (74%)	

TABLE 5 Additional comments made by women on the animation

Positive comments (N = 100)	Frequency, n (%)	Negative comments (N = 21)	Frequency, n (%)
Very informative	22 (22%)	Did not like style of cartoon	11 (52%)
Like the diverse characters depicted	8 (8%)	Insufficient Information	7 (33%)
Simple/clear/easy to understand	29 (29%)	Too quick	2 (9%)
Reassuring	13 (13%)	Animation should have subtitles	1 (5%)
Destigmatizing	8 (8%)		
Positive style/tone of animation	13 (13%)		
Animation better than text	7 (7%)		

We acknowledge that recall of information may be high at a single timepoint shortly after information delivery, compared with an interval or serial timepoints to assess recall. However, abortion care is not a long-term condition and EMA treatment is usually completed within 48 hours of the consultation.

During a standard consultation, more is inevitably discussed than the key information assessed in the study, but this finding suggests the animation could replace some of the detailed information giving during a standard consultation.

In other observational studies,^{2,4} the objective was not to replace a clinical consultation altogether and, likewise, we would not recommend this based upon the findings of the current study. This study was not designed to detect superiority of the animation. Rather we would advise using the animation as an adjunct to the standard EMA process. The animation could be played in the waiting room of a

clinic or made available on a clinic website, so that it could be viewed more than once to reinforce the information given. This approach is already used by services in the UK to provide information about vasectomy⁷ and intrauterine contraceptive insertion.⁸ It can also be viewed by partners, care-givers and friends to allow them to provide better support to the woman and to improve community knowledge of the subject.

The advantages of using an animation to provide clinical information is that it ensures high quality, standardized information can be provided consistently to all patients and it is independent of provider knowledge or bias and patient literacy levels. By designing an animation such as this to include a diverse range of characters, in terms of age, body shape, race and religion, inclusive messaging for a wide range of patients and settings can be provided. In a qualitative study using animation to

provide experiential information about EMA, women preferred an animation to a video showing live actors, as the animation allowed them to project themselves onto the character and identify more strongly with her.⁹

The findings of the study could be generalized to other high- and low-resource settings, where internet access or smartphone ownership is common.¹⁰ Mobile phone health (m-Health) interventions are increasingly being used and studied in low- and middle-income countries for all aspects of healthcare, particularly contraception^{11,12} and abortion care.^{13,14} m-Health interventions can comprise smartphone apps, text messaging (SMS), telephone conversations and links to webpages, such as the animations used in this study.

The animations include general information about EMA, but there are points that are country-specific, reflecting differences in legislation. This would limit the use of the animations in their current form to the countries in the study, ie Sweden, France and UK. If the audio component were translated and adapted appropriately, as with this study, we would expect these findings to be reproducible in other settings.

This particular animation discusses gestational dating by ultrasound and contact with the abortion clinic and so would need to be modified for use in settings where abortion is restricted or illegal. There are videos produced by the International Planned Parenthood Federation that provide experiential information about abortion in several languages and specifically in settings where abortion is illegal or highly taboo.¹⁵⁻¹⁸ However, these videos do not provide a step-by-step guide as to what to expect from EMA, as the animation in this study does, but rather focus on the inequity and danger of illegal and unsafe abortion.

Due to the pragmatic "consortium" structure of the study, there are unavoidable variations in standard clinical practice and community knowledge and acceptability of abortion. This may explain the difference in inter-site recall scores. Alternately, this may be explained by the variation in some baseline characteristics, such as smoking status, which may indicate differences in educational and socioeconomic background. Alternatively, the type of woman who volunteers to participate in research studies may be different in different countries and may not be representative of women seeking abortion more generally. Another limitation was a variation in randomization practice between sites. This occurred due to variation in local ethical review board and departmental research and development advice, and further justifies our emphasis on results in each individual site rather than combined across sites.

5 | CONCLUSION

This study demonstrates that women's recall of key information on EMA did not differ between information delivered by the short animation or a standard face-to-face consultation. There was also high acceptability for use of the animation to deliver information on EMA. We recommend the use of animation to provide information to

patients in advance of their attendance at an abortion clinic in order to improve their baseline knowledge, provide a better foundation for informed consent and thus improve their experience of medical abortion.

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CONFLICT OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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